REMARKS

Claims 1-6 are pending in the application. With entry of the instant amendment, claim 1 has been amended to reflect that the *Bacillus anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein is in an amount sufficient to elicit a cytotoxic T lymphocyte (CTL) immune response. This amendment adds no new matter. Support can be found, *e.g.*, in the specification on page 6, lines 22-24, which defines a unit dose as "a defined and predetermined concentration or amount of the vaccine that is a safe and therapeutically effective amount, which produces the desired results, *e.g.*, an immune response"; and page 4, lines 5-6, which indicates that the compositions of the invention target the cell-mediated immune system. Additional support can be found, *e.g.*, in the passage starting at page 17, line 20, which teaches how to assay CTL responses *in vitro* and *in vivo* (page 19).

Rejection under 35 U.S.C. § 103

The claims stand rejected as unpatentable over Leppla *et al.*, WO94/18332 (referred to herein as "Leppla"). The Examiner alleges that in view of the teachings of Leppla, it would have been obvious to optimize the composition to obtain the molar ratio recited in claim 1. The rejection further contends that the intended use carries no patentable weight because the claimed product is the same as an optimized product of Leppla. To the extent that the rejection applies to the amended claims, Applicants respectfully traverse. The rejection has not established a reason, based on the teachings of Leppla, why one of skill would have been motivated to produce the particular compositions claimed here.

Claim 1 recites that the amount of *Bacillus anthracis* anthrax protective antigen and full length protein bound to an anthrax protective antigen binding protein is a unit dose, *i.e.*, an amount sufficient to elicit an immune response. While the current invention is generically encompassed by the binary toxins/pharmaceuticals of Leppla, the *specific* compositions, which comprise an amount sufficient to induce a CTL response, are not rendered obvious by Leppla. As noted by the Examiner, Leppla teaches pharmaceutical compositions comprising the

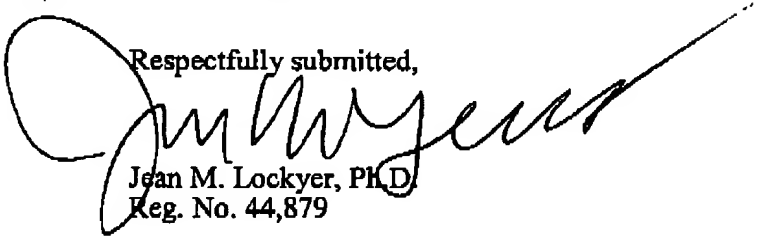
components of a binary toxin system and that such compositions can be optimized. Further, Leppla teaches that the components of the system are administered in an amount sufficient to bind to the cells and result in internalization of the active moiety such that the activity is performed within the cell (page 25, lines 31-38 of Leppla). Leppla also teaches at page 27 that generally, the dosage will approximate that which is typical for the administration of cell surface receptor ligands, preferably in the range of about 2 μg/kg/day to 2 mg/kg/day. However, Leppla does not teach or suggest that the amount of compositions should be an amount sufficient to induce an immune response. The rejection provides no evidence or reasoning that would lead one of skill to this particular formulation. Accordingly, a prima facie case of obviousness has not been established. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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